REMARKS

Claims 1, 2, 24, 31, 38, 64, and 65 are pending and are rejected.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 64 and 65 are rejected under 35 U.S.C. §112 ¶1 as not described, specifically, that claim 64 comprises new matter. The Examiner states that "the specification does not provide support for the recitation that the formulation is administered [in] six applications for about three minutes each or 1-10 applications a day" and "the entire range of 1-10 applications is not disclosed."

Applicant respectfully asserts that "six applications for about three minutes each" is supported at least on p. 22 Example 1 lines 1-7, and that the range of "1-10 applications a day" is supported at least on p. 16 lines 19-21. U.S. Patent No. 5,981,256, which is incorporated by reference in its entirety, describes application of a composition "1-10 times a day, depending on the type, severity and localization of the lesions (col. 18 lines 17-19).

Hence, Applicant respectfully requests that the rejection be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1, 2, 24, 31, 38, 64, and 65 are rejected under 35 U.S.C. §103(a) as obvious over SU 1685448 in view of Zaias, Rawlings, and Burbach. Applicant respectfully disagrees.

It is the Examiner's position that SU 1685448 teaches the "treatment of seborrheic keratosis by topical application of a composition containing the hydrolase trypsin, at a concentration selective for regulating depth of skin treatment, as well as regulating removal of the swelled layer. As there is removal of the swelled layer, there is removal of seborrheic keratosis."

In contrast to SU 1685448, Applicant's invention "consists essentially" of trypsin. It does not contain an anti-inflammatory such as theophylline, or other components, as in SU 1685448. It is known to one skilled in the art that symptoms of skin inflammation include redness, swelling, irritation, etc. In fact, the amount of theophylline used in the ointment composition of example 2 of SU 1685448 was increased from 16 g to 176 g after 10 days. The amount of trypsin was substantially the same (0.04 g) for the first 10 days and 0.05 g during the follow-up two week period. There was no regression of swelling during the first 10 days, but there was regression after the amount of theophylline was increased more than 10 fold. Hence, Applicant asserts that a person of ordinary skill in the art would not predict any connection between removal of the swelling, and removal of the lesion. Further, a person of ordinary skill in the art, based on the teachings of SU 1685448, would not know the bona fide active in the composition, because the swelling regressed only after the amount of theophylline was substantially increased.

Further in contrast to SU 1685448, Applicant's invention does not require occlusion for therapy. Page 3 of SU 1685448 discloses "In all cases, the ointment was applied for a period of 1 to 2 days, and covered with an occlusive dressing." As known to a person of ordinary skill in the art, occlusion enhances skin hydration. In addition, the lanolin and sunflower oil components of the SU 1685448 composition have occlusive properties, similar to petrolatum (see Kligman, Cosmetics and Toiletries 93 (1978) pp. 27-35, and Prottey et al. British Journal of Dermatology 94 (1976) pp.13-21, of record as

submitted in Applicant's December 20, 2005 Amendment. All claims are now amended to recite that the application may be direct, or may be indirect via bandage, dressing, or covering, supported at least in FIGS. 1-4 and at p. 20 lines 13-17:

> The application may be performed in any manner that is suitable to the individual and/or the type of composition, and may additionally involve an application device. The composition may be applied directly or indirectly, such as by a dressing, bandage, covering, etc.

Thus, Applicant respectfully asserts that a person of ordinary skill in the art would be taught that increased skin hydration is required for treating seborrheic keratosis, based on SU 1685448.

Regarding Zaias, the Examiner's position is that DMSO is a known skin irritant and that one of ordinary skill in the art would have a reasonable expectation of success by using only trypsin as the active ingredient and that DMSO serves as a carrier of the SU 1685448 actives. Applicant respectfully asserts that it is unclear in SU 1685448 the "carrier" role of DMSO for its composition and that Zaias teaches a method and composition for skin depigmentation. Zaias does not provide a teaching for removing skin lesions with trypsin.

The Examiner provides Rawlings "to show a trypsin-containing composition applied to the skin which does not comprise DMSO, thus demonstrating that DMSO is not required for the activity of trypsin on the skin." Hence, Applicant restates the argument on page 5, 3rd paragraph, of Applicant's Amendment filed May 30, 2007 (dated January 25, 2007). Briefly, Rawling teaches a use for stratum corneum trypsin-like enzyme (SCTE) for the "alleviation or prevention of dry flaky skin conditions", not for treating seborrheic keratosis.

The Examiner provides Burbach to show "that the administration of a composition consisting essentially of trypsin had been previously taught. Thus, there is no reason to conclude that the presence of DMSO is necessary for the administration of trypsin to skin in the teaching in SU'448 of treating seborrehic keratosis." Applicant restates the argument on page 5 ¶4 of Applicant's Amendment filed May 30, 2007 (dated January 25, 2007). Briefly, Applicant uses different trypsin concentrations than Burbach. Burbach also teaches away from Applicant's method because Burbach teaches the use of trypsin to form a lesion (i.e., blisters), not to treat or remove a seborrheic keratotic lesion.

For at least these reasons, Applicant asserts that the primary reference alone fails, and that a person of ordinary skill in the art would not combine the secondary references to result in Applicant's method. Even if combined, there would be no reasonable expectation of success, at least because one would think (1) additional components, other than the enzyme, are needed for efficacy, (2) occlusion is required for efficacy, and (3) there is a chance that additional lesions would form.

In contrast, Applicant recites a method requiring only the enzyme as the active, not requiring occlusion (e.g., alleviating the need for bandaging), and without additional lesion formation.

Applicant believes that these rejections are overcome and respectfully request their withdrawal.

CONCLUSION

Applicant asserts the application is in complete condition for allowance. No fees are believed due but, if deemed necessary, the Office is authorized to charge them to Deposit Account No. 28-0809.

The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,

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